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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,280	03/17/2004	Yasuo Urata	227832	3630
23460	7590	02/26/2007	EXAMINER	
LEYDIG VOIT & MAYER, LTD			HENLEY III, RAYMOND J	
TWO PRUDENTIAL PLAZA, SUITE 4900			ART UNIT	PAPER NUMBER
180 NORTH STETSON AVENUE			1614	
CHICAGO, IL 60601-6731				
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	02/26/2007		PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/802,280	URATA ET AL.	
	Examiner Raymond J. Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 November 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-53 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-53 is/are rejected.  
 7) Claim(s) 45 and 48-50 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**CLAIMS 1-53 ARE PRESENTED FOR EXAMINATION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Because this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' submission filed on November 20, 2006, which includes amendments to claims 1, 16, 25, 34 and 44, a declaration under 37 C.F.R. § 1.131 of Yasuo Urata and Tomohiro Ishikawa, ("Urata et al. declaration") and remarks, has been entered.

Applicants' remarks and the Urata declaration have overcome the rejections based on Gumkoski et al., (U.S. Patent Application Publication No. 2006/0014788). Further, in view of the remarks and amendments, the rejections not reiterated from the previous office action are hereby withdrawn. The following rejections are reiterated and constitute the totality of issues remaining in the present application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Objection***

Claims 45 and 48-50 are objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, for the reasons of record as set forth in the previous Office action dated August 23, 2006 at pages 2-3, as applied to claims 48-50.

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Applicants' remarks pertaining to the identity of the claims subject to this objection at page 10 of their amendment have been noted. In response, the Examiner notes that the claims were not properly identified. As noted above, claims 45 and 48-50, which depend from claim 44 defining a kit, should have been set forth. The Examiner regrets the confusion. The reasons set forth in the previous Office action properly apply to present claims 45 and 48-50 and such claims are deemed properly objected to. The following are those reasons set forth in the previous Office action.

By amendment to claims 48-50 dated June 9, 2006, Applicants have indicated that the prescribing information contained in the kit of claim 44 includes specific information for the patient concerning the administration of the claimed designated compound. Further, Applicants have currently amended claim 44 to indicate that in the prescribing information, food is not part of the pharmaceutical composition.

The subject matter of claims 48-50 is not deemed to be further limiting of the kit of claim 44, which provides for prescribing information, because the written material on the prescribing information is not subject to patent laws, or at the least is only a statement of intended use, and thus does not impart any further physical or otherwise material feature to the kit of claim 44. Such would be considered a further limitation if the written material were not simply matter printed on the substrate, but rather were of a type of written material such as the digits imprinted on the band of a mathematical device considered in the decision of *In re Gurlack*, 217 USPQ 401 (CAFC 1983). Also, while written material may properly be recited in a claim, as noted above, the specific printed information is not material covered under patent laws, but rather copyright

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laws. In this respect, because such matter is not statutory, it is not seen as further limiting subject matter.

Further supporting the Examiner's position that written material on prescribing instructions which are a part of a kit fail to represent a patentable limitation, MPEP § 2112.01(III) is noted where it is set forth "Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004), (Claim at issue was a kit requiring instructions and a buffer agent. The Federal Circuit held that the claim was anticipated by a prior art reference that taught a kit that included instructions and a buffer agent, even though the content of the instructions differed.)".

In order to overcome this ground of objection, Applicants may wish to consider amending claim 44 to include, by way of Markush language, the requirements of claims 48-50.

For the above reasons, the claims are believed to remain properly objected to.

#### ***Double Patenting***

**I** Claims 44-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 U.S. Patent No. 6,426,365 (Shinkai et al., cited by Applicants, see the IDS filed April 12, 2004, cit. "AA"), claims 1-7 of U.S. Patent No. 6,753,346, (Shinkai et al., cited by Applicants, see IDS filed October 13, 2004, Doc. No. "BT"), **or provisionally rejected** on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-22 of U.S. Patent Application No. 10/825,531, (Attorney Docket listed as 06501-036002 and which has an assignee common to the present application,

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i.e., Japan Tobacco), for the reasons of record as set forth in the previous Office action at pages 8-9 as applied to claims 1-53, which reasons, to the extent that they address the patented/co-pending claims defining a composition and the present claims defining a kit, are here incorporated by reference, in further view of Remington's Pharmaceutical Sciences, ("Remington's"; newly cited by the Examiner).

Applicants' remarks have been carefully considered, but fail to persuade the Examiner of error in his determination.

It remains the Examiner's position that from the subject matter of the patented/co-pending claims, the presently claimed kit would have been obvious to one of ordinary skill in the art. The subject matter written upon the prescribing information means has been noted, but is not deemed a patentable limitation, (MPEP § 2112.01(III)).

In further support that a kit comprising a composition comprising the claimed designated active and an instruction means would have been obvious, the Examiner newly relies on Remington's Pharmaceutical Sciences where it is indicated that a label for or labeling of pharmaceutical compositions are required. For example, at page 1855, col. 1, the middle of the first paragraph, it is set forth that "[l]abeling was first regulated by the Sherley Amendment to the Food and Drug Act, which congress enacted in 1912". Also, at column 2, third paragraph the meaning of "label" and "labeling" are set forth. Given that the compositions of patented/co-pending claims were for pharmaceutical purposes, the inclusion of a packaging material and a labeling means with instructions for use would have been readily recognized as necessary by one of ordinary skill in the art.

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**II** Claims 1-53 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 11-23 of co-pending Application No. 10/802,220 **or** claims 1-5, 7-32, 34-52, 54-83 of co-pending Application No. 10/835,916, each of record, for the reasons of record as set forth in the previous Office action at pages 22-24, which reasons are here incorporated by reference.

Applicants have considered the present, provisional rejection and have decided to address such rejections at the time the cited applications issue as patents. Insofar as arguments pointing out any alleged errors in the present rejection, or a terminal disclaimer, have been presented, the rejection is deemed properly maintained.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Raymond J. Henley III  
Primary Examiner  
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February 17, 2007